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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,997	12/04/2003	Tricia J. Vos	MPI02-196PIRNM	7133
26694	7590	02/22/2006	EXAMINER	
VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20045-9998			GRAZIER, NYEEMAH	
			ART UNIT	PAPER NUMBER
			1626	
DATE MAILED: 02/22/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/727,997	Applicant(s) VOS ET AL.	
	Examiner Nyeemah Grazier	Art Unit 1626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 2-6 and 23-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 7 is/are rejected.
- 7) ☒ Claim(s) 8-22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/5/04, 11/5/04</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**  
**FIRST ACTION ON THE MERITS**

**I. ACTION SUMMARY**

Claims 1-32 are currently pending. Claims 2-6, 23-32 are withdrawn from further consideration by the Examiner because Claims 2-6, 23-32 are drawn to a non-elected invention. 37 C.F.R. § 1.142(b).

**II. PRIORITY**

This application claims benefit and priority to U.S. Provisional Application 60/430,789, filed December 4, 2002.

**III. INFORMATION DISCLOSURE STATEMENT**

The information disclosure statements (IDS) submitted on April 5, 2004 and November 5, 2004 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

**IV. RESTRICTION/ELECTION**

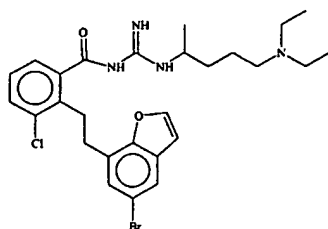
***A. Election: Applicant's Response***

Applicant's election of Group I, claims 1-22 in the response filed on November 28, 2005 is acknowledged.

Group II, drawn to claim 21 has been rejoined with Group I because the amended claim 21 now depends from claim 1.

***B. Status of the Claims***

i. Scope of the Elected Subject Matter



Applicant has provisionally elected with traverse the above compound as a specie.

The scope of the elected subject matter is the compound of formula (I) wherein:

A ring is a phenyl ring; B ring is a benzofuranyl;; Q is alkyl; X is oxygen; G is G2 wherein L2 is C<sub>2</sub>-C<sub>6</sub> alkylidene; and R<sup>4</sup> and R<sup>5</sup> are as recited in claim 1 EXCEPT that R<sup>4</sup> and R<sup>5</sup> may not form a 4 to 14 member ring..

ii. Extended Prior Art Search M.P.E.P. §803.02

If upon examination of the elected species, no prior art is found that would anticipate or render obvious the instant invention based on the elected species, the search of the Markush-type claim will be extended. See M.P.E.P. § 803.02 (2001). If prior art is then found that anticipates or renders obvious the non-elected species, the Markush-type claim will be rejected. It should be noted that the prior art search will not be extended unnecessarily to cover all non-elected species. Should Applicant overcome the rejection by amending the claim, the amended claim will be reexamined. Id. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. Id. In the event prior art is found during reexamination that renders obvious or

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anticipates the amended Markush-type claim, the claim will be rejected and the action made final. Id.

As indicated above, Examiner searched the compound based on the elected species, above in response to the requirement to restrict the products of Formula (I). However, there was no prior art of record that anticipated or rendered obvious the elected species and therefore the scope of the subject matter was **extended or broaden** in pursuant to M.P.E.P. § 803.02.

The prior art search was extended to include compounds and compositions of formula (I) wherein: A ring is a thienyl or phenyl ring; B ring is a benzofuranyl, or phenyl; Q is C<sub>2</sub>-C<sub>4</sub> alkylidene; X is sulfur or oxygen; G is G<sub>2</sub> or G<sub>3</sub> wherein L<sub>2</sub> is C<sub>2</sub>-C<sub>6</sub> alkylidene wherein the alkylidene chain is optionally interrupted by the group listed in claim 1 and L<sub>3</sub> is a direct link; R<sub>14</sub> is hydrogen or aliphatic; and R<sup>4</sup> and R<sup>5</sup> may form a 4-14 member ring containing nitrogen.

iii. Non-elected Subject Matter Withdrawn 37 C.F.R. §1.142(b)

The scope of the non-elected subject matter are compounds and compositions of formula (I) wherein A is 6 member ring with 1-2 nitrogen atoms or a five member heteroaryl other than thienyl; B is 6 member ring with 1 or 2 nitrogen atoms optionally substituted with one or more R<sub>8</sub> groups; Q is a C<sub>2</sub>-C<sub>4</sub> alkylidene chain wherein a methylene unit of the chain is replaced by S, SO, SO<sub>2</sub>, NR<sub>1</sub>, O, CO or CS; and where G is G<sub>1</sub> and where G is G<sub>3</sub> and L<sub>3</sub> is other than a direct link and R<sub>14</sub> is other than hydrogen or aliphatic.

**V. REJECTION(S)**

**35 USC § 103 - OBVIOUSNESS REJECTION**

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

*Graham v. John Deere Co.* set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. § 103(a). *See Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 7 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent 5,693,672 (Weichert et al.).

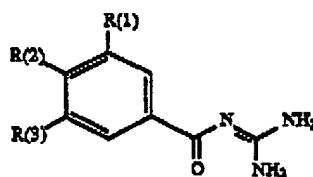
The instant invention discloses compound and compositions of formula I. The compounds have utility as melanocortin-4 receptor modulators and therefore may pharmaceutically efficacious in treating cardiovascular disorders, neuronal disorders and inflammation, for example. The invention particularly encompasses compounds of formula I

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wherein G is G3 and L3 is a linker and R1, R2, R3 and R14 are hydrogen atoms making an acylguanidine.

**The Scope and Content of the Prior Art (MPEP §2141.01)**

*Weichert, et al.* teaches substituted benzoylguanidines (below) and their use as a medicament for treating arrhythmia, ischemia of the nervous system. In addition the compounds of the invention are useful in treating cell proliferation where cell proliferation is the primary or secondary cause. (See *Weichert et al.*, col. 5, ll. 44-67; col. 6, ll. 1-38).



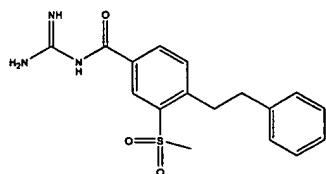
**The Difference Between the Prior Art and the Claims (MPEP §2141.02)**

The difference between the prior art of *Weichert, et al.* and the instant invention is that the instant invention is a positional isomer of the prior art. Both inventions are used to treat neuronal disorders, cardiovascular conditions for example.

**Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)**

The instant invention is structurally similar to Example 7, 3-methylsulfonyl-4-[(2'-phenyl)ethyl]benzoylguanidine and its salt form. (col. 9, line 23).

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Nevertheless, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make a isomers thereof. Ortho substitution for a known compound which is the position (para position) isomer as taught in Weichert et al. renders the instant invention obvious because such structurally similar related compounds suggest one another and would be expected to have similar properties absent a showing of unexpected results. See *In re Norris*, 84 USPQ 458 (1950).

The motivation to make the instant invention is derived from the teachings of the prior art. Specifically, the prior art teaches a specie drawn to the instant invention wherein both ring A and ring B are phenyl, ring a is substituted by R7 wherein R7 is SO<sub>2</sub>Me; G is G3 and R1, R2, R2 and R14 are hydrogen; L3 is a direct link; Q is C2 alkylene or alkyl and ring B is unsubstituted. The prior art teaches the positional isomer of the instant invention and generally teaches the activity of the compounds.

## VI. OBJECTION(S)

### Dependent Claim Objections

Dependent Claims 8-11-22 are also objected to as being dependent upon a rejected based claim. To overcome this objection, Applicant should rewrite said claims in an independent form and include the limitations of the base claim and any intervening claim.



*Claim Objection-Non Elected Subject Matter*

Claims 1, and 7-22 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should rewrite the claims deleting all the non-elected subject matter and leaving only the variables directed solely to the subject matter indicated as being examinable, *supra*.

**VII. ALLOWABLE SUBJECT MATTER**

The allowable subject matter are the compound and compositions for formula (I) wherein:

A ring is a thienyl or phenyl ring;

B ring is a benzofuranyl, or phenyl;

Q is C<sub>2</sub>-C<sub>4</sub> alkylidene;

X is sulfur or oxygen;

G is G<sub>2</sub>;

L<sub>2</sub> is C<sub>2</sub>-C<sub>6</sub> alkylidene wherein the alkylidene chain is optionally interrupted by the group listed in claim 1;

R<sub>4</sub> and R<sub>5</sub> are as recited in claim 1.

**VIII. CONCLUSION**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Thursday and every other Friday from 8:30 a.m. - 6:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,



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